

## United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

· ·				
APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,083	09/09/2003	Simon Delagrave	20446-002001 / BTS0001-10	2730
26161 FISH & RICHA	7590 10/29/200 ARDSON PC	7	EXAMINER	
P.O. BOX 1022	2		STEELE, AMBER D	
MINNEAPOLIS, MN 55440-1022		-90-	ART UNIT	PAPER NUMBER
			1639	•
			MAIL DATE	DELIVERY MODE
			10/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

# Advisory Action

Application No.	Applicant(s)		
10/659,083	DELAGRAVE, SIMON .		
Examiner	Art Unit		
Amber D. Steele	1639		

Before the Filing of an Appeal Brief --The MAILING DATE of this communication appears on the cover sheet with the correspondence address --THE REPLY FILED 04 October 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. 1. X The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods: The period for reply expires \_\_\_\_ months from the mailing date of the final rejection. b) The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f). Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). **NOTICE OF APPEAL** 2. The Notice of Appeal was filed on . A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a). **AMENDMENTS** 3. The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because (a) They raise new issues that would require further consideration and/or search (see NOTE below); (b) They raise the issue of new matter (see NOTE below); (c) They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or (d) They present additional claims without canceling a corresponding number of finally rejected claims. NOTE: see attached "Advisory Action Continued". (See 37 CFR 1.116 and 41.33(a)). 4. The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324). 5. Applicant's reply has overcome the following rejection(s): 6. Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s). 7. X For purposes of appeal, the proposed amendment(s): a) X will not be entered, or b) . will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended. The status of the claim(s) is (or will be) as follows: Claim(s) allowed: Claim(s) objected to: Claim(s) rejected: 61-69. Claim(s) withdrawn from consideration: \_\_\_\_ AFFIDAVIT OR OTHER EVIDENCE 8. The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e). 9. The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1). 10. The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached. REQUEST FOR RECONSIDERATION/OTHER 11. M The request for reconsideration has been considered but does NOT place the application in condition for allowance because: Please refer to the attached "Advisory Action Continued". 12. \( \subseteq \text{Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). mula 13. Other: MARK L. SHIBUYA

PRIMARY EXAMINER

The amendment filed October 4, 2007 under 37 CFR 1.116 in reply to the final rejection has been considered but is not deemed to place the application in condition for allowance and will not be entered because of the following:

- a. The proposed amendment requires further consideration and/or search (i.e. the new limitation "and wherein said parent neutralizing agent is a protein comprising a PDZ domain" in independent claim 61).
- b. The proposed amendment may necessitate the modification of outstanding rejection(s) to address the new limitation (i.e. the new limitation "and wherein said parent neutralizing agent is a protein comprising a PDZ domain" in independent claim 61).
- c. The proposed amendment may necessitate the raising of new prior art rejections (i.e. the new limitation "and wherein said parent neutralizing agent is a protein comprising a PDZ domain" in independent claim 61).
- d. There is no convincing evidence under 37 CFR 1.116(b) why the proposed amendment was not earlier presented.
- e. Applicant's arguments of the prior art of record (i.e. Rosin et al., Eaton et al., and Karrer et al.) are moot since the arguments are based on the proposed amendments that have not been entered.

### Arguments and Response

Applicant's arguments directed to the rejection under 35 USC 102 (b) as being anticipated by Staudinger et al. for claims 61-62 and 64-65 were considered but are not persuasive for the following reasons.

Application/Control Number: 10/659,083

Art Unit: 1639

Applicant contends that Staudinger et al. fails to teach coevolution methods for countering resistance, selecting one or more next generation neutralizing agents...from diversified poplations...wherein the selected one or more neutralizing agents...have improved neutralizing activity" which applicant asserts would require an experiment testing binding of PICK1 mutants with PKCα mutants in the Staudinger et al. reference, or broad neutralizing activity.

Applicant's arguments are not convincing regarding claims 61-62 and 64-65 since the teachings of Staudinger et al. anticipate the method of the instant claims. Staudinger et al. teach producing PKCα mutants, PKC isoforms, PICK1-like PDZ domains, and PICK1 mutants (i.e. diversifying target and neutralizing agent) and various binding assays including determining binding of PICK1 to PKCα, PKCα mutants, and PKC isoforms; determining binding of PICK1-like protein (i.e. PICK mutant) to PKCα and PKCα mutants (i.e. applicant's required experimental test of binding between PICK1 mutants and PKCα mutants; coevolution); and determining binding of PICK1 mutants to the PKCα catalytic domain (i.e. applicant's required experimental test of binding PICK1 mutants to PKCα "mutants" wherein the truncation of PKCα is considered a "mutant" PCKα; coevolution) wherein "selection" occurs via analyzing the results for positive or negative binders (please refer to the entire specification particularly the abstract; Figures 1-3 and 5-6; pages 32021-32022).

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e. screening diversified targets for binding to diversified neutralizing agents wherein the screen occurs at the same time and not in separate steps) are not recited in the rejected claim(s). Although the claims

Art Unit: 1639

are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The present method comprises two method steps which are (a) diversifying a target and a neutralizing agent and (b) selecting a target and a neutralizing agent.

In response to applicant's arguments, the recitation "coevolving" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

#### Withdrawn Rejection

Applicant's arguments regarding broad neutralizing activity (i.e. PKC7 is the catalytic domain of PKCα) are persuasive. Thus, the rejection of claim 63 under 35 USC 102 (b) as being anticipated by Staudinger et al. is withdrawn in view of applicant's persuasive arguments.

#### Conclusion

For all the reasons above, the amendment does not place the application in better condition for allowance and/or appeal.

#### Future Communications

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amber D. Steele whose telephone number is 571-272-5538. The examiner can normally be reached on Monday through Friday 9:00AM-5:00PM.

Application/Control Number: 10/659,083 Page 5

Art Unit: 1639

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Doug Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ADS October 15, 2007

MARK L. SHIBUYA
PRIMARY EXAMINER